CARACO PHARMACEUTICAL LABORATORIES LTD
Form 10-Q
August 10, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
for the transition period from_____ to _____

for the quarterly period ended June 30, 2009

Commission File No. 001-31773

CARACO PHARMACEUTICAL LABORATORIES, LTD.
(Exact name of registrant as specified in its charter)

MICHIGAN	38-2505723
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
1150 ELIJAH MCCOY DRIVE, DETROIT, MICHIGAN	48202
(Address of principal executive offices)	(Zip Code)

TELEPHONE: (313) 871-8400
Registrant's telephone number, including area code

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes o No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or

a smaller reporting company. See the definition of “large accelerated filer”, “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ¨ Accelerated Filer x Non- Accelerated Filer ¨ Smaller Reporting Company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ¨ No x

As of August 7, 2009 the registrant had 39,090,194 shares of common stock issued and outstanding.

CARACO PHARMACEUTICAL LABORATORIES LTD.
(A subsidiary of Sun Pharmaceutical Industries Limited)
BALANCE SHEETS

	June 30, 2009 (UNAUDITED)	MARCH 31, 2009 (AUDITED)
ASSETS		
Current assets		
Cash and cash equivalents	$ 55,061,829	$ 65,314,397
Short-term investments	10,000,000	—
Accounts receivable, net	7,336,304	15,181,197
Inventories	108,165,831	79,510,832
Prepaid expenses and deposits	9,807,147	9,440,942
Deferred income taxes	3,373,369	416,985
Total current assets	193,744,480	169,864,353
Property, plant and equipment		
Land	975,311	975,311
Buildings and improvements	28,353,101	28,148,447
Equipment	27,496,755	26,216,521
Furniture and fixtures	1,505,540	1,509,582
Construction in progress	2,641,627	2,708,137
Total	60,972,334	59,557,998
Less accumulated depreciation	15,701,181	14,734,961
Net property, plant and equipment	45,271,153	44,823,037
Intangible assets, net	1,358,784	1,383,048
Deferred income taxes	22,486,833	20,417,885
Total assets	$ 262,861,250	$ 236,488,323
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable, trade	$ 3,807,675	$ 7,979,341
Accounts payable, Sun Pharma	84,246,452	43,928,166
Accrued expenses	2,320,936	2,757,361
Long term debt, current portion	18,000,000	2,700,000
Total current liabilities	108,375,063	57,364,868
Long term debt, net of current portion	—	15,300,000

Total liabilities	108,375,063	72,664,868
Stockholders' equity		
Series B convertible preferred stock, no par value; issued and outstanding 2,176,000 shares (June 30, 2009), 2,720,000 shares (March 31, 2009)	18,702,720	23,081,920
Common stock, no par value; authorized 50,000,000 shares, issued and outstanding 38,002,194 shares (June 30, 2009), 37,458,194 shares (March 31, 2009)	122,948,535	118,569,335
Additional paid in capital	3,560,029	3,474,246
Retained earnings	9,274,903	18,697,954
Total stockholders' equity	154,486,187	163,823,455
Total liabilities and stockholders' equity	$ 262,861,250	$ 236,488,323

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.
(A subsidiary of Sun Pharmaceutical Industries Limited)
STATEMENTS OF OPERATIONS

	Three months ended June 30,	
	2009 (UNAUDITED)	2008 (UNAUDITED)
Net sales	$48,070,016	$ 108,276,740
Cost of goods sold	51,679,584	84,693,329
Gross (loss) profit	(3,609,568)	23,583,411
Selling, general and administrative expenses	3,659,211	3,818,002
Research and development costs - other	7,085,135	5,484,229
Operating (loss) income	(14,353,914)	14,281,180
Other (expense) income		
Interest expense	(130,950)	-
Interest income	104,455	277,773
Loss on sale of equipment	(114,272)	-
Other income	46,298	-
Other (expense) income - net	(94,469)	277,773
(Loss) income before income tax (benefit) expense	(14,448,383)	14,558,953
Income tax (benefit) expense	(5,025,332)	5,118,888
Net (loss) income	$(9,423,051)	$ 9,440,065
Net (loss) income per common share		
Basic	(0.25)	0.29
Diluted	(0.25)	0.23

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.
(A subsidiary of Sun Pharmaceutical Industries Limited)
STATEMENTS OF CASH FLOWS

	Three months ended June 30,	
	2009 (UNAUDITED)	2008 (UNAUDITED)
Cash flows from operating activities		
Net (loss) income	$ (9,423,051)	$ 9,440,065
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities		
Depreciation and amortization	1,116,015	653,053
Loss on sale of equipment	114,272	-
Common stock option expense	85,783	64,605
Common stock grant expense	-	169,900
Net deferred income taxes	(5,025,332)	(825,465)
Changes in operating assets and liabilities which provided / (used) cash:		
Accounts receivable	7,844,893	55,363,710
Inventories	(28,655,000)	68,063,053
Prepaid expenses and deposits	(366,205)	(2,011,847)
Accounts payable	36,146,619	(164,589,253)
Accrued expenses	(436,425)	332,384
Income taxes payable	-	5,944,353
Net cash provided by (used in) operating activities	1,401,569	(27,395,442)
Cash flows from investing activities		
Purchases of property, plant and equipment	(1,654,447)	(5,513,331)
Proceeds from sale of equipment	310	-
Purchase of short-term investment	(10,000,000)	-
Purchases of intangibles	-	(1,100,000)
Net cash used in investing activities	(11,654,137)	(6,613,331)
Cash flows from financing activities		
Proceeds from exercise of stock options	-	11,250
Net cash provided by financing activities	-	11,250
Net decrease in cash and cash equivalents	(10,252,568)	(33,997,523)
Cash and cash equivalents, beginning of period	65,314,397	56,906,051
Cash and cash equivalents, end of period	$ 55,061,829	$ 22,908,528

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.
(A subsidiary of Sun Pharmaceutical Industries Limited)
STATEMENT OF STOCKHOLDERS' EQUITY (UNAUDITED)

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID IN	RETAINED	TOTAL STOCKHOLDERS'
	SHARES	AMOUNT	SHARES	AMOUNT	CAPITAL	EARNINGS	EQUITY
Balances at April 1, 2009	2,720,000	$23,081,920	37,458,194	$118,569,335	$3,474,246	$18,697,954	$ 163,823,455
Conversion of preferred stock into common stock	(544,000)	(4,379,200)	544,000	4,379,200	-	-	-
Common stock options expensed	-	-	-	-	85,783	-	85,783
Net loss	-	-	-	-	-	(9,423,051)	(9,423,051)
Balances at June 30, 2009	2,176,000	$18,702,720	38,002,194	$122,948,535	$3,560,029	$9,274,903	$ 154,486,187

See accompanying notes

CARACO PHARMACEUTICAL LABORATORIES, LTD.

FORM 10-Q

NOTES TO UNAUDITED FINANCIAL STATEMENTS

1. BASIS OF PRESENTATION

The balance sheet as of March 31, 2009 is audited. All other financial statements contained herein are unaudited. In the opinion of management, all adjustments necessary for a fair presentation of such financial statements have been included. Such adjustments consisted only of normal recurring items, with the exception of a reserve for inventory seized by the U.S. Food and Drug Administration ("FDA"), as discussed below. Interim results are not necessarily indicative of results for the full year.

The financial statements contained herein should be read in conjunction with the financial statements and notes thereto included in the Annual Report on Form 10-K as of and for the year ended March 31, 2009 of Caraco Pharmaceutical Laboratories, Ltd. ("Caraco," the "Company," or the "Corporation" and which is also referred to as "we," "u or "our"). In preparing these financial statements, the Company has evaluated events and transactions for potential recognition or disclosure through August 7, 2009, the date the financial statements were available to be issued.

The accounting policies followed by the Corporation with respect to the unaudited interim financial statements are consistent with those stated in the Corporation's Annual Report on Form 10-K.

2. ORGANIZATION AND NATURE OF BUSINESS

Caraco is a corporation organized under Michigan law in 1984, engaged in the business of developing, manufacturing, marketing and distributing generic and private-label pharmaceuticals to the nation's largest wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers, throughout the U.S.

A generic pharmaceutical is the chemical and therapeutic equivalent of a brand-name drug as to which the patent and/or market exclusivity has expired. Generic pharmaceuticals are well accepted for substitution of brand pharmaceuticals (which substitution is regulated by individual state regulations) as they sell at a discount to the branded product's price and have been determined to be their equivalent in quality and bioavailability.

Our present product portfolio includes 32 prescription products, in 78 strengths, in various package sizes. This represents products we distribute for Sun Pharmaceutical Industries Limited, a specialty pharmaceutical corporation organized under the laws of India ("Sun Pharma") and products manufactured by other third parties relating to Caraco owned products. The products are intended to treat a variety of disorders including but not limited to the following: hypertension, arthritis, epilepsy, diabetes, depression and pain management.

A significant source of our earlier funding had been from Sun Pharma. Since August 1997, Sun Pharma has contributed equity capital and had advanced us loans. In addition, among other things, Sun Pharma

had acted as a guarantor on loans to Caraco, has supplied us with a substantial portion of raw materials for our products, helped us obtain machinery and equipment to enhance our production capacities at competitive prices, transferred certain generic products to us and provided us with qualified technical professionals. Sun Pharma has also provided services as a Clinical Research Organization, ("CRO") by performing certain bio-equivalency studies on our future potential products. Sun Pharma owns approximately 75% of the outstanding shares of the Company (approximately 76% including the convertible Series B Preferred Stock). (See "Current Status of the Corporation" and "Sun Pharmaceutical Industries Limited" below.)

3. CURRENT STATUS OF THE CORPORATION

On June 25, 2009, U.S. Marshals, at the request of the FDA, arrived and seized drug products manufactured in our Michigan facilities. The seizure also included ingredients and in-process materials held at these same facilities. The estimated value of such seized inventory as of June 30, 2009 was $22.9 million. The Company is in the process of negotiating with the FDA to ascertain how much of such inventory it will be allowed to recondition and utilize in the future. The FDA stated that the drug products are adulterated in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and/or holding do not conform to and are not operated and administered in conformity with current good manufacturing practice ("cGMP") requirements. Products sold and distributed by Caraco that are manufactured outside of these facilities are not impacted. As a result of the FDA action, we have voluntarily ceased manufacturing operations and instituted an indefinite reduction in our workforce of approximately 350 employees. As a result of this event, there has been a material adverse effect on our current operations and may be a material adverse effect on our near term operations. While we believe that we have taken corrective actions and that continual improvements are in process in response to past FDA observations from past inspections as disclosed in our prior SEC filings, we also believe that we may need to take additional steps to correct our methods, facilities and controls used to manufacture, process, pack, label, hold and distribute pharmaceutical products which are manufactured at our Michigan facilities. There is no assurance that the steps taken will be successful or result in resolution of the FDA complaint. We are also not able, at this time, to estimate, the cost of these actions. We anticipate working with the FDA to resolve its concerns as effectively and expeditiously as possible.

During the first quarter of our new fiscal year ("Fiscal 2010") ended June 30, 2009, we generated net sales of $48.1 million compared to $108.3 million during the corresponding period of Fiscal 2009. We incurred $7.1 million in research and development ("R&D") expenses during the first quarter of Fiscal 2010, as compared to $5.5 million during the corresponding period of Fiscal 2009. We generated cash from operations in the amount of $1.4 million during the first quarter of Fiscal 2010, as compared to using cash from operations in the amount of $27.4 million during the corresponding period of Fiscal 2009. We incurred a net pre-tax loss of $14.4 million during the first quarter of Fiscal 2010, as compared to net pre-tax income of $14.6 million during the corresponding period of Fiscal 2009. Net pre-tax income was lower as we have created a reserve in the amount of $8.4 million at June 30, 2009 relating to the inventory seized by the FDA, as mentioned above. During the first quarter of Fiscal 2010, we provided for an income tax benefit of $5.0 million, as compared to an income tax expense of $5.1 million in the corresponding period of Fiscal 2009. We incurred a net loss of $9.4 million during the first quarter of Fiscal 2010, as compared to net income of $9.4 million during the corresponding period of Fiscal 2009. At June 30, 2009, we had stockholders' equity of $154.5 million, as compared to stockholders' equity of $163.8 million at March 31, 2009. (See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.").

We did not file any Abbreviated New Drug Applications ("ANDAs") with the FDA during the first quarter of Fiscal 2010. We have not received FDA approval for any ANDAs during the first quarter of Fiscal 2010 and do not expect to receive any approvals for products out of our Detroit facility until we resolve the FDA's concerns as discussed above. The total number of ANDAs pending approval by the FDA as of June 30, 2009 was 29 (including four tentative approvals) relating to 25 products.

4. RECENT ACCOUNTING PRONOUNCEMENTS

In May 2009, the FASB issued SFAS No. 165, "Subsequent Events" ("SFAS 165"), which provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS 165 is effective for interim or fiscal periods ending after June 15, 2009 and became effective for the Company beginning with its quarterly period ended June 30, 2009. Its adoption did not have an impact on the Company's results of operations, financial position or cash flows.

In July 2009, the FASB issued SFAS No. 168, "FASB Accounting Standards Codification" ("SFAS 168"), as the single source of authoritative nongovernmental U.S. generally accepted accounting principles ("GAAP"). The Codification is effective for interim and annual periods ending after September 15, 2009 and will become effective for the Company beginning with its quarterly period ending September 30, 2009. All existing accounting standards are superseded as described in SFAS 168. All other accounting literature not included in the Codification is non-authoritative. The Company is currently evaluating the impact of the adoption of SFAS 168 but does not expect the adoption of SFAS 168 to have a material impact on the Company's results of operations, financial position or cash flows.

5. COMPUTATION OF EARNINGS PER SHARE

Earnings per share is computed using the weighted average number of common shares outstanding during each period and considers a dual presentation and reconciliation of "basic" and "diluted" per share amounts. Diluted reflects the potential dilution of all common stock equivalents.

The basic and diluted weighted average numbers of common shares outstanding for the first quarter of Fiscal 2010, ended June 30, 2009, were both 37,547,864. Correspondingly, the basic and diluted weighted average numbers of common shares outstanding for the first quarter of Fiscal 2009, ended June 30, 2008, were 32,677,391 and 40,536,369, respectively.

6. SUN PHARMACEUTICAL INDUSTRIES LIMITED

Pursuant to a stock purchase agreement, Sun Pharma made an initial investment of $7.5 million for the purchase of 5.3 million common shares of Caraco in 1997.

In August 1997, Caraco entered into an agreement, whereby Sun Pharma was required to transfer the technology formulas for 25 generic pharmaceutical products over a five-year period in exchange for 544,000 shares of Caraco common stock for each technology transfer of an ANDA product (when bio-equivalency studies were successfully completed) and 181,333 common shares for each technology transfer of a Drug Efficacy Study Implementation ("DESI") product. The products provided to the Corporation from Sun Pharma were selected by mutual agreement. Under such agreement, Caraco

conducted, at its own expense, all tests including bio-equivalency studies. Pursuant to such agreement through 2002, Sun Pharma delivered the technology formula for 13 products. This agreement expired on November 21, 2002, and the Corporation entered into a new technology transfer agreement with Sun Pharma Global, Inc. ("Sun Global"), an affiliate of Sun Pharma.

Under the agreement, which was approved by the Corporation's independent directors, Sun Global agreed to provide the formulations for 25 new generic drugs over a five-year period. Caraco's rights to the products are limited to the United States and its territories or possessions, including Puerto Rico. Sun Global retains rights to the products in all other territories. The products are selected by mutual agreement. Under this agreement, Caraco conducts at its own expense all tests, including bio-equivalency studies. The Corporation also markets the products consistent with its customary practices. In return for the technology transfer, Sun Global receives 544,000 shares of Series B Convertible Preferred Stock for each generic drug transferred when such drug has passed its bio-equivalency studies.

The products agreement was amended by the Independent Committee, comprised of the three independent directors, in the first quarter of 2004 to eliminate the provision requiring that the Independent Committee concur in the selection of each product, and provides instead that each product satisfy certain objective criteria developed by management and approved by the Independent Committee. Pursuant to such objective criteria, all 25 of the products under this agreement had been selected, and all 25 products had passed their respective bio-equivalency studies as of March 31, 2008.

Sun Pharma operates research and development centers in Mumbai and Vadodara in India, where the development work for products is performed.

Sun Pharma and its subsidiaries supply the Corporation with certain raw materials and formulations, assist in acquiring machinery and equipment to enhance production capacities, and have provided qualified technical professionals who work as Caraco employees. Sun Pharma continues to provide Clinical Research Services on a product by product basis. Also, five of the nine directors of Caraco are, or were, affiliated with Sun Pharma.

Further, Sun Pharma and its affiliates may use Caraco as a contract manufacturer and/or distributor of their products. In December 2004 and January 2005, Caraco entered into agreements for two such products, of which one is currently being marketed.

During the fiscal year ended March 31, 2007 ("Fiscal 2007"), the Corporation entered into a three-year marketing agreement with Sun Pharma, which was reviewed and approved by the Board's Independent Committee. Under the agreement, the Corporation purchases selected product formulations offered by Sun Pharma and markets and distributes the same as part of the current product offerings in the U.S., its territories and possessions, including Puerto Rico. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco.

During the fiscal year ended March 31, 2008 ("Fiscal 2008"), the Corporation entered into a three-year distribution and sale agreement with Sun Pharma, which was reviewed and approved by the Board's Independent Committee. Under this agreement the Company purchases selected formulations which have been filed under Paragraph IV certification process with the FDA by Sun Pharma and offered for distribution. Paragraph IV certified ("Para IV") products may face litigation challenges with respect to

claims of patent infringement. Under the agreement the Company shares in the sales opportunity and shares the litigation risk. The Company is indemnified by Sun Pharma of any risk beyond the percentage agreed to as its profit percentage thereby limiting the Company's exposure. Sun Pharma is not obligated to offer Caraco products under this agreement, however, Caraco has the exclusive right to market in the U.S., its territories and possessions, including Puerto Rico, any products offered by Sun Pharma and accepted by Caraco. The Company markets and distributes the same as part of its current product offerings in the U.S., its territories and possessions, including Puerto Rico. The license granted with respect to a product terminates upon the end of an exclusivity period of 180 days or a non-appealable court decision, or until a third generic manufacturer launches the product, whichever is later, or until a settlement is reached, at which time the product will become part of the standard Caraco-Sun Pharma marketing agreement disclosed above. The Company currently receives a fixed gross profit margin of 8%, or such other percentages as shall be mutually agreed upon. Under the agreement, Sun Pharma and Caraco mutually indemnify each other capped by the fixed margin percentage with respect to damages from infringement.

During the quarters ended June 30, 2009 and June 30, 2008, the Corporation made net sales of $35.0 million and $76.2 million of the marketed products under aforesaid agreements, respectively.

While management has a basis to reasonably believe that Sun Pharma's substantial investment in Caraco provides Sun Pharma with sufficient economic incentive to continue to assist Caraco in developing its business, and Sun Pharma has expressed its intent to continue to support Caraco's operations in the near term, as it has done in the past, there can be no assurance that such support will, in fact, continue.

During the first quarter of Fiscal 2010, Sun Global converted 544,000 shares of Series B Preferred Stock into 544,000 shares of Common Stock and subsequent to the end of first quarter Fiscal 2010, Sun Global converted 1,088,000 shares of Series B Preferred Stock into 1,088,000 shares of Common Stock. Through March 31, 2009 Sun Global had converted 10,880,000 shares of Series B Preferred Stock into 10,880,000 shares of Common Stock, respectively. Sun Pharma's current beneficial ownership is 75% (76% including its convertible Series B Preferred Stock).

In addition to its substantial relationship with, and dependence on Sun Pharma as described above, the Corporation is subject to certain risks associated with companies in the generic pharmaceutical industry. Profitable operations are dependent on the Corporation's ability to market its products at reasonable profit margins. In addition to maintaining profitable operations, the ongoing success of the Corporation will depend, in part, on satisfaction of FDA concerns, its continuing ability to attract and retain key employees, obtain timely approvals of its ANDAs, and develop new products.

7. ACCOUNTING FOR STOCK BASED COMPENSATION

The Company follows the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123 (Revised 2004), "Share-Based Payment" ("Statement No. 123 (R)"), which requires employee share-based compensation to be accounted for under the fair value method and requires the use of an option pricing model for estimating the fair value of stock options at the date of grant. The Company estimates the fair value of stock options granted using the Black-Scholes option-pricing model, which requires the Company to estimate the expected term of the stock option grants and expected future stock price volatility over the term. The term represents the expected period of time the Company believes the options will be outstanding based on historical information. Estimates of expected future stock price

volatility are based on the historical volatility of the Company's common stock. The Company calculates the historical volatility as the standard deviation of the differences in the natural logarithms of the weekly stock closing price, adjusted for dividends and stock splits.

For the first quarter of Fiscal 2010, the Company has recognized expenses amounting to $85,783 related to common stock options as compared to $64,605 for the corresponding period of Fiscal 2009. As of June 30, 2009, total unrecognized compensation cost related to stock options granted was $423,497. The unrecognized stock option compensation cost is expected to be recognized over a period of approximately three years. Additionally, during the first quarter of Fiscal 2009, the Company recorded an expense of $169,900 related to a stock grant of 10,000 common shares issued to its CEO on May 2, 2008, as part of his employment agreement, which vested immediately upon issuance.

8. COMMON STOCK ISSUANCES

There were no common stock issuances to Directors or employees during the first quarter of Fiscal 2010. We issued 1,000 shares of common stock to our employees upon exercise of their stock options during the first quarter of Fiscal 2009. Also, during the first quarter of Fiscal 2009, the Company issued a stock grant of 10,000 common shares to its CEO on May 2, 2008, as noted above.

During the first quarter of Fiscal 2010, Sun Global converted 544,000 shares of Series B Preferred Stock into 544,000 shares of Common Stock. Subsequent to the end of the first quarter of Fiscal 2010, Sun Global converted 1,088,000 shares of Series B Preferred Stock into 1,088,000 shares of Common Stock. (See "Part II – Other Information: Item 2. Unregistered Sales of Equity Securities and Use of Proceeds" below).

9. PREFERRED STOCK ISSUANCES

No shares of preferred stock were issued during the first quarters ended June 30, 2009 or June 30, 2008.

10. SALES AND CUSTOMERS

Sales on distributed products were significantly lower in comparison to the first quarter of Fiscal 2009 primarily as a result of significantly higher sales of Para IV product during the first quarter of Fiscal 2009. See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – First Quarter Fiscal 2010 Compared to First Quarter Fiscal 2009." Sales on distributed products were also lower due to price erosion on the products sold. Otherwise, sales on distributed products remain fairly stable and we continue to remain competitive on distributed products we have sold and marketed during the first quarter of Fiscal 2010. However, during the quarter, sales of our manufactured products were adversely affected due to the negative impact of our voluntary recalls and, in part, by the actions of the FDA and the cessation of manufacturing, as disclosed above. Our organization is focused on correcting any and all manufacturing issues to allow us to emerge as a stronger company. In the interim, we will continue to focus our sales and marketing team on distributed product sales.

As is typical in the U.S. retail sector, many of our customers are serviced through their designated wholesalers. During the first quarter of Fiscal 2010, the Company's three largest wholesale customers, Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for

approximately 10%, 10% and 8%, respectively, of the Company's total net sales. During the corresponding period of Fiscal 2009, shipments to Amerisource-Bergen Corporation, McKesson Corporation and Cardinal Health, accounted for approximately 6%, 20% and 9%, respectively, of the Company's total net sales. The majority of these net sales include sales for various customers of ours that have underlying direct contracts with our Company that are facilitated through our wholesale customers. During the first quarter of Fiscal 2010, sales to CVS Caremark Corporation accounted for approximately 38% of our net sales. The sales to CVS Caremark Corporation have increased as we have recently entered into a new contract with it.

11. DEBT

As a consequence of the FDA actions disclosed above, on June 29, 2009, JP Morgan Chase Bank N.A. ("JP Morgan") temporarily suspended the Company's $10 million Credit Agreement until such time as the matters with the FDA are resolved to the satisfaction of the Bank or such Credit Agreement expires. The Credit Agreement is set to expire on November 30, 2009. However, there were no borrowings under the Credit Agreement at any time during the quarter ended June 30, 2009. Under the Credit Agreement, JP Morgan may make loans and issue letters of credit to the Corporation for working capital needs and general corporate purposes. Letters of credit, if issued, expire one year from their date of issuance, but no later than November 30, 2009. Borrowings are secured by the Corporation's receivables and inventory. Interest is payable based on a LIBOR Rate or an alternate base rate (determined by reference to the prime rate or the federal funds effective rate), as selected by the Corporation. The rate of interest is LIBOR plus 75 basis points, or the bank's prime rate minus 100 basis points (provided the prime rate is not less than the prevailing one month LIBOR Rate plus 250 basis points). The effective rates were 1.35% and 2.25%, respectively, at June 30, 2009. The Credit Agreement requires that certain financial covenants be met on a quarterly basis.

During the fourth quarter of Fiscal 2009 the Company entered into a term loan of $18 million with RBS Citizens, N.A. d/b/a Charter One Bank ("Charter One Bank"). The loan is secured by a mortgage covering the Company's manufacturing facility and equipment located in Detroit, Michigan. The rate of interest is calculated as LIBOR plus an applicable margin thereto (based upon various leverage levels and current applicable rate is 50 basis points). The aggregate rate applicable to the Company as of June 30, 2009 was 2.01%. The principal loan payments and accrued interest are payable on a quarterly basis beginning July 2009. The principal is to be repaid in equal quarterly installments of $900,000 for ten quarters through October 2011, and thereafter, if not renewed, the remaining balance of $9 million is due in January 2012. Subsequent to the end of first quarter Fiscal 2010, Charter One Bank has issued a technical default letter to the Company because of the FDA actions. We have entered into discussions with Charter One Bank to resolve its concerns. We anticipate either entering into revised agreements or repaying the loan in full. Currently, as the loan is in default, the entire outstanding balance has been classified as a short-term liability.

As required pursuant to the terms of the Loan Agreement, the Company has entered into an Interest Rate Swap Agreement with Charter One Bank to hedge the interest rate applicable on the loan. The notional amount for the swap is $18 million which will amortize down as principal payments are made on the related debt. The annualized fixed rate of interest as it applies to this agreement is 2.41%. Thus as of June 30, 2009 the effective rate of interest to the Company for the term loan was 2.91% (2.41% swap rate plus applicable margin of 50 basis points). The fair value of this swap agreement at June 30, 2009 was not material.

12. LITIGATION

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. An adverse outcome in any of these proceedings could have a material adverse effect on the Company's financial position and results of operations.

As previously disclosed, on June 9, 2005, Novo Nordisk A/S and Novo Nordisk, Inc. ("Novo Nordisk") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company's filing of an ANDA seeking approval to market its generic version of Novo Nordisk's Prandin® (repaglinide) drug product infringed Novo Nordisk's U.S. Patent No. 6,677,358. Novo Nordisk seeks an order from the Court which, among other things, directs the FDA not to approve the Company's ANDA any earlier than the claimed expiration date. The ANDA filed by the Company contains a Paragraph IV certification challenging the Novo Nordisk patent as well as a section viii statement with regard to the patent's method claim. The Company believes that this Novo Nordisk patent is invalid and/or will not be infringed by the Company's manufacture, use or sale of the product. The Company believes that it is the first to file an ANDA with a Paragraph IV certification for this drug product and it intends to defend this action vigorously to capitalize on the potential for obtaining 180 days exclusivity available for this product. The Company has filed a motion for summary judgment of non-infringement, which has been stayed pending resolution of its supplemented answer and counterclaim challenging Novo Nordisk's recent Orange Book use code amendment by Novo Nordisk in reference to Prandin®. Trial should occur in the fall of 2009.

As previously disclosed, on July 10, 2006, Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S (collectively, "Forest") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company's filing of an ANDA seeking approval to market its generic version of Forest's Lexapro® (escitalopram oxalate) drug product infringed Forest's Patent No. Re. 34,712 (the "'712 patent"). The ANDA contains Paragraph IV Certifications challenging the '712 patent, as well as two other Forest-owned patents, the 6,916,941 ("the '941 patent") and 7,420,069 ("the '069 patent"). Forest did not assert the '941 patent or '069 patent, so the Company brought declaratory judgment actions seeking a declaration that it did not infringe those patents. The Company vigorously litigated all three cases.

On July 10, 2009, the Company announced that it has reached an agreement with Forest to settle the Lexapro® litigation. As part of that settlement:

1. Forest has agreed to provide licenses to the Company for any patents related to Lexapro® with respect to the marketing of the Company's generic version of the product as of the date that any third party generic enters the market with final approval from the FDA other than an authorized generic or the first filer with Hatch-Waxman exclusivity.

2. Forest will reimburse the Company for a portion of its attorney's fees related to this litigation.

3. Forest Laboratories, Inc. and the Company have entered into an Asset Purchase Agreement (the "APA"). Under the APA, the Company will take over the commercialization and sale of several products from Forest's Inwood business. Caraco will pay Forest an advance against royalties and royalties on net sales of these products.

The terms of the settlement have been submitted to the Federal Trade Commission and the Department of Justice pursuant to the Medicare Modernization Act. The APA is scheduled to close no sooner than 40 days after receipt of the documents by the FTC and DOJ, which the parties hope will provide the agencies with sufficient time to review the transaction. As the transaction must be submitted to the FTC and DOJ, there is a possibility that the transaction may need to either be revised, or it may not be consummated, and the litigation would be re-instituted.

As previously disclosed, on September 22, 2004, Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil") filed a complaint in the United States District Court for the Eastern District of Michigan alleging that the Company's filing of an ANDA seeking approval to market its generic version of Ortho-McNeil's Ultracet® brand tramadol/acetaminophen drug product infringed Ortho-McNeil's patent, which expires on September 6, 2011. Ortho-McNeil sought an order from the district court which, among other things, directed the FDA not to approve the Company's ANDA any earlier than the claimed expiration date. The ANDA filed by the Company contains a Paragraph IV Certification challenging the Ortho-McNeil patent. The Company asserted that the Ortho-McNeil patent is invalid and/or will not be infringed by the Company's manufacture, use or sale of the product. Since filing this action, Ortho-McNeil authorized a generic manufacturer to provide a generic version of Ortho-McNeil's Ultracet® product while another manufacturer launched its approved generic at risk. On October 19, 2005, the Company's motion for summary judgment was granted. On December 19, 2005, the FDA approved the manufacture, use and sale of the Company's generic product. Ortho-McNeil filed an appeal of the finding of noninfringement by the district court with the United States Court of Appeals for the Federal Circuit. On January 19, 2007, the United States Court of Appeals for the Federal Circuit affirmed the lower court's decision granting the Company's motion for summary judgment.

Additionally, the United States Patent and Trademark Office approved Ortho-McNeil's request for a reissue patent. Although the district court had determined that the Company does not infringe Ortho-McNeil's original patent, on July 31, 2006, Ortho-McNeil filed a lawsuit against the Company in the United States District Court for the District of New Jersey, alleging that the Company's generic version of Ultracet® brand tramadol/acetaminophen drug product infringes its reissue patent. On September 26, 2006, the Company filed an answer denying, among other things, that its generic product infringes any valid claims of Ortho-McNeil's reissue patent. On December 10, 2007, the Company filed a motion for summary judgment that the asserted claims of the reissue patent were obvious and therefore invalid as a matter of law. This motion was granted by Judge Cavanaugh of the District of New Jersey on April 17, 2008. Final judgment has been granted. On August 25, 2008, Ortho-McNeil filed a notice of appeal with respect to that judgment with the United States Court of Appeals for the Federal Circuit. The appeal has been fully briefed and was argued on July 7, 2009.

As previously disclosed, on February 24, 2009, MedImmune, LLC filed a complaint against the Company and Sun Pharma in the United States District Court for the District of Maryland. The complaint alleged that Caraco infringed U.S. Patent Nos. 5,424,471 and 5,591,731 by offering to sell or selling a generic version of the drug Ethyol® in the United States. The Company denied infringement and contended that the patents in suit are invalid and unenforceable. The Complaint is related to MedImmune Oncology, Inc. v. Sun Pharmaceuticals Industries Ltd., 1:04-cv-02612-MJG, which involves the same patents. Effective July 31, 2009, MedImmune, LLC, Sun Pharma, and the Company, entered into a Settlement and License Agreement (the "Settlement") to resolve this litigation. Under the Settlement, MedImmune granted Sun Pharma and its affiliates (including Caraco) a license to continue to market a generic version of Ethyol®. The terms of the settlement have been submitted to the Federal Trade Commission and the Department of Justice pursuant to the Medicare Modernization Act.

As previously disclosed, on May 5, 2009, Wyeth filed a complaint against the Company and Sun Pharma in the United States District Court for the Eastern District of Michigan. The complaint alleges that the package insert for Sun Pharma's product that is distributed by the Company and which is a generic version of Wyeth's Protonix® (pantoprazole) pharmaceutical product contains false and misleading statements regarding the active ingredient of that product in violation of federal and state laws. The complaint requests damages, injunctive relief and attorneys' fees and costs. The Company and Sun Pharma believe that they have not engaged in any improper conduct and intend to vigorously contest these allegations. On July 6, 2009, the Company and Sun Pharma filed a Motion to Dismiss the Complaint for Failure to State a Claim Upon Which Relief May Be Granted.

On June 25th, 2009, at the direction of the FDA, the U.S. Marshal Service, arrived and seized drug products manufactured, work in process materials, and ingredients held, at the Company's Michigan facilities. The estimated value of such seized inventory as of June 30, 2009 was $22,939,316. The office of the United States Attorney, on behalf of the FDA and Department of Justice, filed a Warrant for Arrest In Rem to seize certain materials at the Company's Michigan facilities in the United States District Court for the Eastern District of Michigan. A Complaint for forfeiture of those materials has also been filed with the court by the FDA. The Complaint alleges that the drug products and materials are adulterated, in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing and holding do not conform to cGMP requirements. This has resulted and will result in a material adverse effect on our current and near term operations. While we believe that we have taken corrective actions and that improvements are in process in response to past FDA observations from past inspections as disclosed in our prior SEC filings, we also believe that we may need to take additional steps to correct our methods, facilities and controls used to manufacture, process, pack, label, hold and distribute pharmaceutical products which are manufactured at our Michigan facilities. There is no assurance that the steps taken will be successful or result in resolution of the FDA complaint. We are also not able, at this time, to estimate, the cost of these actions. We intend to continue to work with the FDA to resolve its concerns as effectively and expeditiously as possible.

On July 17, 2009 and July 23, 2009, two purported class action lawsuits were filed in the United States District Court – Eastern District of Michigan against the Company and certain of its executive officers. The lawsuits allege securities violations related to the Company's public statements on FDA compliance issues made between May 29, 2008 and June 25, 2009. The Company believes the allegations to be without merit and intends to vigorously defend itself.

The Company is also involved in certain other legal proceedings from time to time incidental to normal business activities. While the outcome of any such proceedings cannot be accurately predicted, the Company does not believe the ultimate resolution of any of these certain existing matters would have a material adverse effect on its financial position or results of operations.

13. INVENTORIES

Inventories consist of the following amounts:

	June 30, 2009	March 31, 2009
Raw materials	$ 19,701,349	$17,954,511
Goods in transit	14,024,648	29,236,869
Work in process	7,093,064	9,279,009
Finished goods (Manufactured)	10,194,512	9,749,721
Finished goods (Distributed)	65,598,792	13,290,722
Inventories before reserves	$ 116,612,365	$79,510,832
Less : Reserve for certain inventory under control of the FDA	8,446,534	-
Total Inventories	$ 108,165,831	$79,510,832

Total inventories at June 30, 2009 and March 31, 2009 includes materials purchased in the amount of $1,412,701 and $2,875,885, respectively, related to products for which the Company has filed ANDAs with the FDA, and the commercial launch of such products will commence once the approvals are received.

As disclosed above, on June 25th, 2009, at the direction of the FDA, the U.S. Marshal Service, arrived and seized drug products manufactured, work in process, and ingredients held, at the Company's Michigan facilities. The estimated value of such seized inventory as of June 30, 2009 was $22.9 million. The Company is in the process of negotiating with the FDA to ascertain how much of such inventory it will be allowed to recondition and utilize in the future. A reserve in the amount of $8.4 million has been created as of June 30, 2009 which consists of work in process relating to those materials which are in various stages of production within our manufacturing facilities, finished goods having a shelf life of one year or less as of June 30, 2009, and those products which will be difficult to recondition. Once we have further understanding and clarity from the FDA on the status of the entire inventory, we will make a determination of whether adjustments to the reserve need to be made. There is no assurance as to the amount of inventory which the Company will be able to recondition and distribute in future. In the event that the amount of inventory which the Company is unable to recondition is greater than the current reserve, the Company will adjust the value of its inventory accordingly in future periods, which would result in a negative impact on the future operating results of the Company.

14. INCOME TAXES

The provision for income taxes is as follows:

	Quarter Ended	
	June 30, 2009	June 30, 2008
Current	$-	$5,944,353
Deferred	(5,025,332)	(825,465)
Total	$(5,025,332)	$5,118,888

The provision for income taxes is different from that which would be obtained by applying the statutory federal income tax rate to income before income taxes. The items causing the difference for the first quarters of Fiscal 2010 and Fiscal 2009, respectively, are as follows:

	June 30, 2009	June 30, 2008
Provision for income taxes at federal statutory rate	$ (5,056,934)	$ 5,095,634
Permanent items and other	31,602	23,254
Income taxes	$ (5,025,332)	$ 5,118,888

Deferred taxes consist of the following:	June 30, 2009	March 31, 2009
Deferred tax assets:		
Net operating loss carryforwards	$ 2,067,668	$ 797,631
Intangibles	25,856,468	26,458,255
Reserve for inventory	2,956,383	-
Other	416,986	417,136
Total deferred tax assets	$ 31,297,505	$ 27,673,022
Deferred tax liabilities:		
Intangibles	$ 4,635,740	$ 6,180,987
Depreciation	801,563	657,165
Total deferred tax liabilities	$ 5,437,303	$ 6,838,152
Net deferred tax assets	$ 25,860,202	$ 20,834,870

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15. SEGMENT INFORMATION

The Company operates in two reportable segments consisting of products that it manufactures on its own, as well as those distributed under various agreements with Sun Pharma and its affiliates and with others. The sales and gross profits earned on these categories of products are as follows

	Quarter Ended June 30, 2009		Quarter Ended June 30, 2008	
Category	Net Sales	Gross Profit	Net Sales	Gross Profit
Manufactured Products	$13,081,187	$(6,892,214)	$32,035,365	$16,387,861
Distributed Products	34,988,829	3,282,646	76,241,375	7,195,550
Total	$48,070,016	$(3,609,568)	$108,276,740	$23,583,411

16. SUBSEQUENT EVENTS

Settlement Agreement

As disclosed under “12. Litigation” above, on July 10, 2009, Caraco entered into a settlement agreement ("Settlement Agreement") with Forest and Sun Pharma, regarding the pending patent litigation arising from the filing by Caraco of an ANDA application to market a generic version of Forest's Lexapro® brand escitalopram oxalate product. As part of the Settlement Agreement, Caraco and Forest entered into an Asset Purchase Agreement dated July 10, 2009. Under the Asset Purchase Agreement, Caraco will take over the commercialization and sale of several products from Forest's Inwood business. Caraco's rights to market the products are subject to certain restrictions on its commercialization of competing products. The closing of the transaction is subject to the satisfaction or waiver of certain conditions as specified in the Asset Purchase Agreement, as disclosed under “12. Litigation” above, including the review of the transaction by the FTC and DOJ. Accordingly, there is a possibility that the transaction may either be revised or not consummated.

Agreement With Alkaloida Chemical Company ZRT

On July 10, 2009, Caraco entered into an agreement with Alkaloida Chemical Company ZRT, a Hungarian corporation ("Alkaloida") and indirect subsidiary of Sun Pharma, pursuant to which Alkaloida will provide for certain products an exclusive, non-transferable license to Caraco to manufacture and market the products in the United States, its territories and possessions, including Puerto Rico. The license for a product is for a period of five (5) years from the commencement of marketing of the product, however, Caraco may extend the license for a further five (5) year period. Alkaloida is required to deliver the product technology for a product as soon as it is developed or available or as agreed to by Caraco and Alkaloida.

The agreement expires five years from the date of approval of the first ANDA, unless renewed or extended for consecutive one (1) year periods, however, the licenses remain valid pursuant to the terms of the agreement. Under certain conditions, the agreement may be terminated in its entirety or with respect to one or more products. The agreement is governed by and construed in accordance with the

laws of the State of Michigan. The agreement was approved by Caraco's Independent Committee comprised of Caraco's four independent directors.

MedImmune Settlement

As disclosed under “12. Litigation” above, effective July 31, 2009, MedImmune, LLC, Sun Pharma, and the Company, entered into a Settlement and License Agreement (the “Settlement”) to resolve certain litigation. Under the Settlement, MedImmune grants, in exchange for certain payments, to Sun Pharma and its affiliates (including Caraco), a license to continue to market a generic version of MedImmune’s drug product Ethyol®.

The foregoing descriptions of the Settlement Agreement, Asset Purchase Agreement, agreement with Alkaloida and the MedImmune Settlement do not purport to be complete and are qualified in their entirety by reference to the text of such agreements, copies of which Caraco intends to file with its Quarterly Report on Form 10-Q for the quarter ending September 30, 2009, requesting confidential treatment for certain portions.

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information that management believes is relevant to an understanding of the Corporation’s results of operations and financial condition. The discussion should be read in conjunction with the financial statements and notes thereto and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the Company’s 2008 Annual Report on Form 10-K as of and for the year ended March 31, 2009 (the “Annual Report”) and the unaudited interim financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

Critical Accounting Policies and Estimates

Our significant accounting policies are described in Note 1 to our financial statements included in our Annual Report. Certain of our accounting policies are particularly important to the portrayal of our financial position and results of operations and require management’s subjective judgments. As a result, these judgments are subject to an inherent degree of uncertainty. In applying these policies, management makes estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. Significant estimates include, but are not limited to, provisions for estimated customer returns, discounts, rebates and other price adjustments, including customer chargebacks, valuation allowances for deferred tax assets, valuation of overhead components in inventory and the reserve for inventory. Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. There have neither been material changes to our critical accounting policies for the periods presented nor any material quantitative revisions to our critical accounting estimates for the periods presented.

Revenue Recognition

Revenue from product sales, both manufactured and distributed, net of estimated provisions, is recognized when there is persuasive evidence that an arrangement exists, shipment of the goods has occurred, the selling price is fixed or determinable, and collectibility is reasonably probable. Our customers consist primarily of large pharmaceutical wholesalers who sell directly into the retail channel, chain drug stores, distributors, and managed care customers. Provisions for sales discounts, and estimates for chargebacks, rebates, and product returns are established as a reduction of product sales revenue at the time revenues are recognized, based on historical experience and current market trends adjusted to reflect known changes in the factors that impact these reserves. These revenue reductions are reflected as a direct reduction to accounts receivable through an allowance.

Chargebacks

Chargebacks represent our most significant provision against gross accounts receivable and related reduction to gross revenue. Chargebacks are retroactive credits given to our wholesale customers that represent the difference between the lower price they sell (contractual price) to retail, chain stores, and managed care organizations and what we charge the wholesaler. We estimate chargebacks at the time of sale for our wholesale customers. We are currently unable to specifically determine whether the amounts allowed in specific prior periods for chargeback reserves have been over or understated. Wholesaler customers who submit chargebacks to the Company do not reference a specific invoice that the chargeback is related to when the chargeback is submitted to the Company. Thus, we cannot determine the specific period to which the wholesaler’s chargeback relates.

We consider the following factors in the determination of the estimates of chargebacks.

1. The historical data of chargebacks as a percentage of sales, as well as actual chargeback reports received from our primary wholesaler customers.

2. Volume of all products sold to wholesaler customers and the average chargeback rates for the current quarter as compared to the previous quarter and compared to the last six month period.

3. The sales trends and future estimated prices of our products, wholesale acquisition cost (WAC), the contract prices with the retailers, chain stores, managed care organizations (end-users), and our wholesaler customer’s contract prices.

4. We utilize remaining inventories on hand at our primary wholesaler customers at the end of the period in the calculation of our estimates.

Such estimated amounts, in addition to certain other deductions, are deducted from our gross sales to determine our net revenues. The amount of actual chargebacks claimed could be either higher or lower than the amounts we accrued. Changes in our estimates, if any, would be recorded in the income statement in the period the change is determined. If we materially over or under estimate the amount that will ultimately be charged back to us by our wholesale customers, there could be a material impact on our financial statements.

Shelf Stock Adjustments

Shelf stock adjustments are credits issued to our customers to reflect decreases in the selling prices of our product. These credits are customary in the industry and are intended to reduce the customers' inventory cost to better reflect current market prices. The determination to grant a shelf stock adjustment to a customer following a price decrease is at our discretion.

Factors considered when recording a reserve for shelf stock adjustments include estimated launch dates of competing products based on market intelligence, estimated decline in market price of our product based on historical experience and input from customers and levels of inventory held by customers at the date of the adjustments as provided by them.

Product returns and other allowances

In the pharmaceutical industry, customers are normally granted the right to return product for credit if the product has not been used prior to its expiration date. Our return policy typically allows product returns for products within a twelve month window from six months prior to the expiration date and up to six months after the expiration date. We estimate the level of sale, what will ultimately be returned pursuant to our return policy, and record a related reserve at the time of sale. These amounts are deducted from our gross sales to determine our net revenues. Our estimates take into consideration historical returns of our products and our future expectations. We periodically review the reserves established for returns and adjust them based on actual experience, if necessary. The primary factors we consider in estimating our potential product returns include shelf life of expiration date of each product and historical levels of expired product returns. In case we become aware of any returns due to product related issues, such information from the customers is used to estimate an additional reserve. The amount of actual product return could be either higher or lower than the amounts we accrued. Changes in our estimates, if any, would be recorded in the income statement in the period the change is determined. If we over or under estimate the quantity of product which will ultimately be returned, there may be a material impact on our financial statements.

Discounts (trade and prompt payment discounts) are accrued at the end of every reporting period based on the gross sales made to the customers during the period and based on their terms of trade. We review the contracts between the customer and us as well as the historical data and percentages to estimate the discount accrual.

Customer rebates are estimated at every period end, based on direct or indirect purchases. If the purchases are direct, the rebates are recognized when products are purchased and a periodic credit is given. For indirect purchases, the rebates are recognized based on the terms with such customer. Medicaid rebates are estimated based on the historical data we receive from the public sector benefit providers, which is based on the final dispensing of our product by a pharmacy to a benefit plan participant.

Doubtful Accounts

Doubtful accounts are estimated based on the data available from external sources, including information on financial condition of customers. Also, a regular review of past due receivables is done on a quarterly basis to identify and make provision for such receivables not expected to be collected.

Gross Sales and Related Allowances

Our gross sales for the first quarter of Fiscal 2010 were $82.4 million as compared to $180.1 million for the corresponding period of Fiscal 2009. Sales allowances, which include chargebacks, returns, discounts, other customary customer deductions and other sales costs, constituted approximately 42% for the first quarter of Fiscal 2010 as compared to 40% for the corresponding period of Fiscal 2009. Net sales for the first quarter of Fiscal 2010 were $48.1 million as compared to $108.3 million for the corresponding period of Fiscal 2009. The primary cause of the increased sales allowances by 2% for first quarter Fiscal 2010 is due to the impact of the increased difference between wholesale acquisition costs (WAC) and the contractual prices at which the wholesalers ship to our end use customers.

The following is a roll forward of the provisions for chargebacks, shelf stock adjustments, returns and allowances and estimated doubtful account allowances during Fiscal 2009 and the first three months of Fiscal 2010.

($ in Thousands)

	Balances at beginning of period	Allowances charged to Gross Sales		Credits taken by customers	Balance at the end of period
		Current Period	Prior Period		
For all of Fiscal 2009					
Chargebacks, rebates & shelf stock adjustments	$78,905	$291,070	-0-	$319,947	$50,028
Returns and other allowances	5,273	19,870	-0-	18,588	6,555
Doubtful Accounts	118	231	-0-	271	78
For the first three months of Fiscal 2010					